horizontal differentiation), which is often cited (beside R&D costs) as the second barrier to entry to the branded market. Here, we have discussed several examples of Cournot model within various ATC4 groups and jurisdictions. We have also critically examined preponderance of »me-too« entries, particularly in the light of an R&D investment of the branded firms. Historically, »me-too« drugs are more ubiquitous than often realized by regulatory agencies, payers, and also the pharmaceutical industry itself. This unfortunately presents an inefficient use of resources as the breakthough innovation is nowadays, in the time of austerity measures, a real necessity. The models that would give incentives to the industry to invest in R&D for breaktrough therapies are possible and would not only contribute to optimization of societal welfare but would also in the long run increase an R&D productivity of branded firms.

PHP230
CELL THERAPIES: ASSESSING THE PATIENT ACCESS OPPORTUNITIES AND CHALLENGES THAT LIE AHEAD
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This poster seeks to highlight the key challenges and opportunities surrounding patient access to innovative cell therapies in the EU5 and US. The findings are based on secondary research of commercialised cell therapies as well as primary research with payers in EU5 and US. Cell therapies have a unique opportunity to improve patient outcomes but face their own set of challenges due to being cell based. As many of these therapies involve manipulation of the patients' own cells before being reintroduced (e.g., ChondroCelect), the associated side effects are likely to be minimal. Other therapies (e.g., gene therapy, Glybera) involve the introduction of foreign genetic material but provide a potential long-term cure. However, there are some important challenges that must be assessed when considering how to commercialise such therapies. In the case of therapies where a patient's cells are manipulated *ex vivo*, who bears the risk if the patient does not receive their individualised treatment? For those therapies that purport to cure disease, how much are health care systems willing to pay for them and what evidence would be required in order to justify a high price? Moreover, for all therapies, there is the uncertainty regarding access pathways: will cell therapies necessarily undergo an HTA evaluation to gain access in the EU? What are the criteria that will be used to determine whether such a therapy is deemed a product (and, hence, undergo an assessment like a regular biopharmaceutical) or a procedure (and likely bypass a national evaluation)? In conclusion, cell therapies face uncertainties in market access and funding due to unestablished pathways for the spectrum of interventions that fit under the cell therapy umbrella. Until frameworks have been put in place, each cell therapy should be assessed individually in order to determine likely pathway to patient access.

PHP231
THE IMPACT OF RECENT GENERIC DRUG PRICE POLICIES ON PHARMACEUTICAL INNOVATION: A THEORETICAL RATIONALE AND PROPOSAL OF A METHOD SUPPORTING INNOVATION IN AREAS OF UNMET MEDICAL NEED
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New discoveries are a critical priority for the pharmaceutical industry, for which the primary aim should be to address unmet medical needs. However, the use of fixed cost-effectiveness (ICER) thresholds for health technology assessment (HTA) may tend to decrease incentives to innovate and affect future treatment options. This presentation highlights, using a case study, the impact of recent generic drug price policies on pharmaceutical innovation in the context of fixed ICER thresholds and proposes a new consideration for the cost-effectiveness analysis (CEA). There is a direct causal relationship between HTA and the market price of a drug; in jurisdictions where HTA agencies apply fixed ICER thresholds as an important reimbursement listing criterion, the incremental cost of a new drug is expected to be proportional to its incremental benefit over the comparator. However, the comparator price is subject to market forces or sudden policies and may change markedly affecting the cost-effectiveness assessment (e.g. where the comparator patent has expired). Since recent generic price regulations (e.g. 18% or 25% of the innovative price in Canada) increased the price gap between drugs' generic and patented versions, it is harder to achieve a sufficient level of incremental benefits in order to offset incremental prices of new treatments. This analysis thus demonstrates that with recent changes in generic drug prices in Canada and other jurisdictions, even promising drugs will have challenges to show attractive ICERs. Traditional decision-making process should be adapted to reflect these changes and to promote innovation in therapeutic fields with unmet medical needs. A compromise would be to include the comparator's patented price in the CEA instead of the generic drug in certain areas of unmet needs. By identifying the relevant disease areas, decison makers and HTA authorities could convey the importance of investing in these therapeutic areas to manufacturers.

PHP232
THE EXPANDING SCOPE OF COMPARATIVE EFFECTIVENESS REVIEWS REQUIRES COLLABORATIVE INFORMATION SYSTEMS SOLUTIONS
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BACKGROUND: The scope of systematic reviews and health technology assessments is rapidly expanding due to increasing demand for more complex models that account for patient, treatment, and trial characteristics, network meta-analyses that include more interventions, and the growing number of clinical trials. By the year 2000, the effort required to publish a typical systematic review had already reached the thousands of person-hours, which were predominantly spent on data acquisition tasks. Innovative solutions are required to prevent the costs of comparative effectiveness research from ballooning out of proportion. **PROBLEM:** Typically only the end product of systematic reviewing, a report summarizing the evidence, is made widely available. However, capturing the intermediate results of literature searching, publication screening, and data extraction has the potential to greatly enhance the efficiency of future reviews. In the face of the increasing scope of systematic reviews, this unnecessary duplication of effort must be eliminated. However, doing so is difficult due to the current culture of data protectionism and a lack of suitable software that enables convenient and useful sharing of the intermediate results. **APPROACH:** Building on our previously published reviews of software for systematic review and trial analytics, the talk identifies the technical and cultural challenges to be met. We propose that a web-based solution enabling the global research community to contribute their intermediate results in exchange for access to the data contributed by others could rapidly gain momentum. Such a system would challenge data protectionism by greatly reducing the level of investment required for data acquisition. **CONCLUSION:** A disruptive web-based system enabling a massively collaborative approach to systematic reviewing can make data protectionism obsolete and eliminate much of the effort required for future systematic reviews.

PHP233
VALUE-BASED PRICING IN THE UK AND POTENTIAL PATIENT ACCESS HURDLES TO INNOVATIVE DRUGS
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The UK government plans to introduce value-based pricing (VBP) for medicines in England and Wales from January 2014, and one of the key tenets of the scheme is to improve patient access to new innovative drugs. This poster aims to explore the extent to which VBP is likely to achieve this goal. To meet this objective, an in-depth review of available literature (including white papers from key stakeholders and scientific publications) was conducted. Targeted interviews with five leading thought-leaders in the implementation of VBP were also conducted to support analysis. Research identified a number of areas of uncertainty in VBP implementation that could detrimentally impact patient access to new drugs. First, the timeline for the VBP negotiation process remains unclear. Currently, it takes NICE on average 48 weeks to issue guidance on a single technology appraisal, which could be extended if a technology is not considered cost-effective. Under VBP, manufacturers will still be required to negotiate their price with the Department of Health if the calculated VBP price by NICE is unfavorable, and the VBP HTA methodology itself could be more complex than the current cost-per-QALY approach. Protracted negotiations could also delay access in Scotland and Northern Ireland. Equally, manufacturers may postpone launch in the UK if they consider VBP a threat in their price corridor in other markets. Finally, it is not clear if additional regional or local level negotiations will take place, which could further delay access. In conclusion, although there is potential for the new adjustable QALY threshold (which remains to be confirmed) to foster innovation, the ability of the new VBP process to expedite patient access remains uncertain.

PHP235
A CHOICE OF BUSINESS FOR THE PHARMACEUTICAL INDUSTRY "SEGURO POPULAR" IN MEXICO
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A choice of business for the pharmaceutical industry "Seguro Popular" in Mexico. Abstract Mexico has various providers of health services each one determined to a sector of the population where we can find the Mexican Social Security Institute (IMSS) that is specifically for workers in the private sector employees and their families, the Institute for security and services social of the State workers (ISSSTE) for workers in the service of the State or public sector and their families starting 2003 ushered to the Seguro Popular that extends to the population without social security or in State of helplessness in these three mentioned health are emerging as institutions providing health services larger Mexico insomuch that by 2013 the Seguro Popular has approximately 54 million affiliates number of successful membership in less than 10 years in a country where there is little more than 110 million of people Seguro Popular is placed, on par with the historic and hegemonic IMSS, as the largest buyer of drugs, aware of this are his consumption figures that since 2008 has been made public, in such data can find that from 2008 to 2012 they have bought 1,241,637,748.68 US Dlls only in drugs consumption regularly since the Seguro Popular has several portfolios of services where separate regular conditions of sufferings of low frequency and high cost and conditions of very low frequency and high cost for children under 5 years who in turn have specific budgets.

DISEASE-SPECIFIC STUDIES

GASTROINTESTINAL DISORDERS – Clinical Outcomes Studies

PGI1
UNDERSTANDING THE EFFECT OF CLOSTRIDIUM DIFFICILE INFECTION ON HOSPITAL MORTALITY IN ENGLAND, THE NETHERLANDS, AND SPAIN
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OBJECTIVES: Increasing rates of *Clostridium Difficile* Infection (CDI), a hospital-acquired infection, has stimulated a number of financial incentives and government sponsored initiatives to quell the spread of the disease. Previous research has shown the impact of CDI on hospital length of stay to attempt to quantify the resource implications. The purpose of this study is to evaluate the impact of CDI on in-hospital mortality. **METHODS:** Data were obtained from national hospital episode databases in England, The Netherlands, and Spain. Only patients over the age of 50 and those diagnosed with diabetes, chronic kidney disease, heart failure, and chronic obstructive pulmonary disease (COPD) were included in the analysis. Cases of CDI were stratified between hospital-onset and community-onset cases. Only those that were assumed to be hospital-onset were included in the analysis. A logistical regression was used to predict the relative effect hospital-onset CDI had on in-hospital mortality. A number of covariates were controlled for including: age, sex, comorbidities, and length of stay but varied between countries depending on the availability of data. **RESULTS:** Patients with hospital-onset CDI had an overall higher mortality rate compared to those who